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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,277	11/14/2003	Minas Theodore Coroneo	Q78501	7510

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EXAMINER

HAND, MELANIE JO

ART UNIT PAPER NUMBER

3761

DATE MAILED: 07/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/712,277

Applicant(s)

CORONEO, MINAS THEODORE

Examiner

Melanie J. Hand

Art Unit

3761

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 10-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>6/28/06</u>   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Response to Amendment***

Claims 10-18 have improper claim status identifiers. These claims were withdrawn from consideration by Examiner in the previous Office action and therefore the proper identifier is "Withdrawn".

### ***Response to Arguments***

Applicant's arguments filed May 9, 2006 have been fully considered but they are not persuasive.

With respect to applicant's arguments regarding the rejection of claim 1, Examiner restates the following from the rejection of claim 1 in the previous Office action: "The second end of tube 2 is located in the anterior chamber 15 through a surgically created opening in the cyclodialysis tract 16. ('087, Col. 3, lines 43-50, 62-65, Col. 4, lines 2-5)". Further, cyclodialysis is a procedure that separates the ciliary body from the scleral spur and creates a pathway between the anterior chamber and suprachoroidal space. Therefore, by teaching that tube 2 is located in the anterior chamber through an opening in a cyclodialysis tract, Joseph necessarily teaches that the tube is adapted to locate the device on the inner surface of the sclera (where the scleral spur projects from) in a suprachoroidal space formed by cyclodialysis, as the choroid is on the inner surface of the sclera.

***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on June 28, 2006 was filed after the mailing date of the Application on November 14, 2003. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Joseph (U.S. Patent No. 4,604,087) in view of Molteno (GB 2,101,891 A).

With respect to **Claim 1**: Joseph teaches an aqueous humor drainage device having drainage tube 2 and drainage body 3. Tube 2 and body 3 are comprised of silicone rubber. Body 3 is a band that is fused or glued to tube 2. The circumference of band 3 is chosen so that it is the correct length to be sutured to sclera 11 of eye 10 at an equatorial position. The second end of tube 2 is located in the anterior chamber 15 through a surgically created opening in the cyclodialysis tract 16 to provide aqueous pressure regulation. (Col. 3, lines 43-50, 62-65, Col. 4, lines 2-5).

Joseph does not teach that tube 2 is fused to a disc or plate. Molteno teaches an ocular drainage device having a tube 12 attached to at one end and opening onto plate 21 wherein the plate has a diameter of 13mm and is capable of being folded to a diameter of 1.5 mm. ('891, Page 1, lines 68,69,90,91) Since Joseph teaches that prior art devices such as that taught by

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Molteno use a plate that is sutured to the sclera as taught by Joseph (Col. 1, lines 63-67), Examiner asserts that suturing a band performs an equivalent function and is therefore simply an alternate method of forming a drainage device for regulating pressure in the ocular cavity. In the instant case substitution of equivalent methods requires no express motivation, as long as the prior art recognizes equivalency, *In re Fount* 213 USPQ 532 (CCPA 1982); *In re Siebentritt* 152 USPQ 618 (CCPA 1967); *Graver Tank & Mfg. Co. Inc. v. Linde Air Products Co.* 85 USPQ 328 (USSC 1950).

With respect to **Claims 2,3,4,5,9**: Joseph teaches that tube 2 has an inner diameter of 0.3 mm (Col. 3, line 47) and, with the aid of a pressure limiting valve in the form of slits in the tube itself (claim 4) (Col. 4, lines 25-30), regulates aqueous flow, therefore the diameter of 0.3 mm is suitable for providing a predetermined resistance to aqueous flow (claim 2). The pressure-limiting valve comprising at least one slit regulates fluid pressure so as to remain in the range of 4-20 mm Hg (claims 3,5). (Col. 4, lines 34-37)

With respect to **Claim 6**: Joseph does not teach a plate and therefore does not teach a plate diameter. Molteno teaches an ocular drainage device having a tube 12 and plate 21 wherein the plate has a diameter of 13mm. Therefore, Molteno does not teach that plate 21 has a diameter that falls in the range set forth in claim 6. However Molteno also teaches that the maximum practical size of said plate 21 is 13.5 mm in that this is the maximum size that an eye similar in size to a human eye can accommodate. Therefore it would be obvious to one of ordinary skill to further modify the diameter of said plate such that its diameter falls in the range set forth in claim 6 to ensure that the patient's eye can comfortably accommodate the device as taught by Molteno.

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Joseph teaches that band 3 has a thickness of 0.75 mm, or 750 microns and therefore does not teach a thickness for said band, which has been established previously herein as an equivalent structure to the plate taught by Molteno, that falls within the range set forth in claim 6. Applicant has not established criticality for this thickness range, and therefore this range of thicknesses for the plate of the claimed invention is considered herein to be an optimization of this property of the plate. Therefore it would be obvious to one of ordinary skill in the art to modify the thickness of the plate taught by Molteno equivalent to the band taught by Joseph so as to fall within the range set forth in claim 6 as this modification would represent a decrease in thickness which would further ensure that the device will fit properly and comfortably in the patient's eye.

With respect to **Claim 7**: Joseph teaches that tube 2 has a length of 24 mm and follows the arc of a circle having a diameter of 30mm. ('087, Col. 3, lines 55-57) As can be seen in Figs. 4 and 5, tube 2 follows that arc for about  $\frac{1}{4}$  of the circle, therefore the remaining length of tube that is analogous to the tube of the claimed invention is in the range of 1-4 mm.

With respect to **Claim 8**: Joseph teaches that tube 2 has an inner diameter of 0.3 mm, or 300 microns, and a wall thickness of 0.175 mm, therefore the outer diameter is 0.475 mm or 475 microns. ('087, Col. 3, lines 45-47)

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie J. Hand whose telephone number is 571-272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TATYANA ZALUKAEVA  
SUPERVISORY PRIMARY EXAMINER



Melanie J Hand  
Examiner  
Art Unit 3761